REMARKS

Claims 1, 3-7 and 21-27 are pending.

1. Substance of March 9, 2006 Examiner Interview:

Applicant wishes to thank Examiner for the helpful suggestions proffered during the Interview. In response to the communication mailed March 31, 2006, the substance of the Interview is described below.

While no explicit agreement was reached, there was a differentiation between structural and functional limitations relative to the claims. There was discussion surrounding the structural nature of the claimed invention and that, should Applicant amend the claims according to the parameters defining the structure of the present invention, such amendments may provide a better description of the present invention. Furthermore, amending the claims to provide a better structural depiction of the present invention may obviate the prior art rejections raised by Examiner.

Applicant has incorporated the substance of the Interview in this present Response and respectfully requests Examiner to consider the present amendments to the claims in light of the Interview of March 9, 2006.

2. Rejection under 35 U.S.C. § 102: Deo et al., Ukkonen et al. and Kuby et al.

Examiner has rejected claims 1, 3-4 and 21-24 under § 102(e) as being anticipated by US Patent No. 5,837,243

("Deo"), as evidenced by Ukkonen et al. ("Ukkonen") and by Kuby et al. ("Kuby"). Examiner is of the opinion that the structure of the fusion protein taught by Deo meets all of the claimed limitations as Applicant's invention. Based on the following arguments, as well as the claims presented as currently amended, Applicant respectfully traverses the rejection as the claims are now patentably distinguishable over the Deo reference.

In order for a reference to qualify as prior art under 35 U.S.C. § 102, the reference must "anticipate" the claimed invention. More specifically, the reference must disclose each and every element of the claimed invention (MPEP § 2131; Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987); Scripps Clinic & Res. Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991); In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997); Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995). The absence of any claimed element in the prior art reference negates anticipation.

Based on the Interview of March 9, 2006, and the substance of the Interview being incorporated into the present amendments of the claims, Applicant respectfully submits amendments directed towards the structural definition of the present invention would be sufficient to overcome the Deo reference. Support for the present amendments to the claims is found throughout the specification. Most notably, at page 27, lines 26-29, there is a description of a preferred embodiment which involves the CDR being replaced with a T cell epitope (either antagonist or agonist). Additionally, the Examples

section of the specification is replete with embodiments describing the modification of the nucleotide sequence coding for the heavy chain of a CDR for the complete replacement of the region with a T cell epitope. Examiner is directed to page 36, lines 22-25, which describe the composition of Ig-PLP1 and Ig-PLP-LR. These are the fusion proteins which have the CDR3 being replaced with the T cell epitope PLP.

Examiner has previously relied on the inherency argument between Deo and the present invention. Specifically, Examiner found that the fusion protein of Deo meets the structural requirements of the present invention and, as such, any function which results from said structure would be inherent. The claims now recite the structural requirement of removing the Ig CDR and replacing said region with a T cell epitope. This requirement is not found within the Deo reference and Applicant respectfully submits this amendment is sufficient to traverse the rejection under §102.

Any discussion into the functional similarities of the two inventions would now be considered moot, as the structural distinctions between Deo and the present invention as claimed are now profound. Ukkonen and Kuby were cited by Examiner to illustrate that it was well known in the art that material internalized via Fc receptor mediated endocytosis is delivered to lysosomes and that MHC class II molecules are loaded with peptides. However, while these references may depict similar pathways which the fusion Ig of the present invention may operate physiologically, such references are obviated in light of

the present amendments to the claims. These recited claims now illustrate structural requirements which were neither considered nor anticipated in Ukkonen and Kuby.

Ukkonen characterizes the internalization and intracellular fate of FcR bound to a variety of complexes in the hopes of identifying the pathway of such multivalent Fab preparations. There is nothing in Ukkonen which anticipates removal of the CDR of an Ig molecule and replacing said region with a T cell epitope in hopes of alleviating the symptoms of an autoimmune disease. Ukkonen only examined the importance of ligand valency versus use of intact Fc domains relative to FcR transport during receptor-mediated endocytosis. As stated above, Ukkonen merely characterizes a particular pathway. It anticipates nothing of the structural requirements of the present invention as claimed.

Similarly, Kuby gives, literally, a scholarly approach to teaching about MHC and antigen presentation. The reference discusses assembly and transport of the MHC molecules and the effect of antigen presentation on MHC activation. This reference is even further removed from the present invention than Ukkonen. Kuby seems to be a general textbook which is ideal for studying models of pathways associated with class I and II MHC transport. As with Ukkonen, Kuby has no bearing on the structural requirements of the present invention. There is no anticipation of the present invention as claimed in that there is no discussion or suggestion of manipulation of an Ig in order to ameliorate particular autoimmune diseases. Especially of significance is the lack of any suggestion of

alteration of the Ig CDR and replacing said region with an epitope having the specificity as defined by the claimed invention.

Claims 1, 3-4 and 21-24 as currently presented reflect the above mentioned structural limitations. As Deo does not anticipate Applicant's invention as claimed, the rejection is therefore rendered improper. Applicant respectfully requests Examiner withdraw the rejection in light of the arguments above and the claims as currently amended.

3. Rejection under 35 U.S.C. § 103: Deo et al in view of Karin et al

The Examiner has rejected claims 1, 5, 21 and 25 under § 103 as being unpatentable over Deo et al in view of Karin et al. Examiner is of the opinion that one of ordinary skill in the art would have been motivated to combine the T cell antagonist peptide derived from myelin basic protein of Karin and insert it into the fusion construct of Deo, thereby arriving at Applicant's claimed invention. Due to the fact that Examiner relied on the supposed mechanistic similarities between Deo and the present invention, the claims as presently recited now obviate use of Deo as a proper reference under §103. Specifically, any discussion of the mechanistic similarities between the two inventions should now be considered moot in light of the present amendments to the claims.

The present invention now requires a structural limitation not present in Deo. Deo neither teaches nor

suggests the present invention as claimed in light of the structural requirement expressed in the claims. Such a requirement obviates Deo as a §103 reference and Applicant respectfully requests Examiner withdraw the rejection in light of the above discussion.

4. Rejection under 35 U.S.C. § 103: Deo et al in view of Kuchroo et al

The Examiner has rejected claims 1, 6, 21 and 26 under § 103 as being unpatentable over Deo et al in view of Kuchroo et al. Examiner is of the opinion that one of ordinary skill in the art would have been motivated to combine the T cell antagonist peptide derived from myelin proteolipid protein of Kuchroo and insert it into the fusion construct of Deo, thereby arriving at Applicant's claimed invention. As explained above, the present amendments to the claims obviate Deo as a proper reference under §103. The claims as currently recited now contain a structural requirement that is neither taught nor suggested in Deo, thus relegating Deo as an improper reference to be cited under §103. Applicant respectfully requests Examiner withdraw the rejection.

5. Rejection under 35 U.S.C. § 103: Deo et al in view of Elliot et al, Kuchroo et al and Karin et al

The Examiner has rejected claims 1, 7, 21 and 27 under § 103 as being unpatentable over Deo et al in view of Elliot et al, Kuchroo et al and Karin et al. As explained above, the present amendments to the claims obviate Deo as a proper reference under §103. The claims as currently

recited now contain a structural requirement that is neither taught nor suggested in Deo, thus relegating Deo as an improper reference to be cited under §103. Applicant respectfully requests Examiner withdraw the rejection.

6. Double Patenting Rejection:

Claims 1, 3-4, 6, 21-24 and 26 stand rejected under obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,737,057 ('057). Examiner finds that the claims of the present invention are not patentably distinct from the '057 patent.

Applicant respectfully submits that based on the claims as currently presented, Examiner should withdraw the double patenting rejection, as the rejection is cured by way of amendments. Specifically, the '057 claims a composition comprising an Ig molecule linked to a T cell antagonist to eventually affect autoreactive T cell in vivo. The patented claims recite that the antagonist peptides to be used come from MBP and PLP, therefore targeting autoreactive T cells in MS. Examiner had argued that the present invention was actually broader in scope because they recited three different autoimmune diseases. The present invention, as currently claimed, is much more specific relative to the structural requirements of the fusion protein. The claims of the present invention now recite the requirement of removal of the CDR and replacement with a T cell epitope. This requirement is not mentioned in the '057 patent.

The patented claims are more general, in that the fusion protein may be made in a variety of ways, so long as the functional aspect remains intact. Thus, there is a deeper level of specificity in the present application relative to the '057 claims, which requires no structural requirement for assembly of the Ig fusion protein.

Applicant respectfully requests Examiner withdraw the double patenting rejection in light of the present amendments to the claims which change the scope of said claims such that they are now patentably distinct from the '057 claims.

Applicant respectfully requests withdrawal of the above identified rejections and allowance of the present application based on Applicant's arguments and amendments. Applicant is thankful for Examiner's comments and suggestions during the Interview of March 9, 2006. The substance of that Interview is embodied in the present response. If there are any questions or comments, Applicant's attorney may be reached at the telephone number state below.

Respectfully submitted,

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